Aberrometry in Patients Implanted With Accommodative Intraocular Lenses

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• PURPOSE: **To evaluate the objective accommodative response, change of aberrations, and depth of focus in eyes implanted with the Crystalens accommodative intraocular lens (IOL) at different accommodative demands.**

• DESIGN: **Prospective, observational study.**

• METHODS: **Eleven cataract patients (22 eyes) who underwent implantation of a Crystalens accommodative IOL, and control groups of 9 normal subjects (17 eyes) and 17 pseudophakic patients (17 eyes) implanted with monofocal IOLs were evaluated. A custom-developed laser ray tracing aberrometer was used to measure the optical aberrations. The monochromatic wave aberrations were described using a sixth-order Zernike polynomial expansion. Measurements were obtained under dilated and natural viewing conditions (for accommodative efforts ranging from 0 to 2.5 diopters [D]). The accommodative response was obtained by analyzing changes in paraxial defocus (associated to changes in defocus) and by evaluating the differences in the effective defocus (associated with defocus, spherical aberrations, and pupil diameter) with the accommodative demand. Depth of focus was estimated from through-focus objective optical quality.**

• RESULTS: **Wave aberration measurements were highly reproducible. Vertical trefoil (Z_3^{-3}) was the predominant higher-order aberration in the Crystalens group and significantly higher ($P < .0001$) than in the young group, but similar to the monofocal IOL group. The coma root mean square also was higher ($P < .005$) in the Crystalens group than in the young group. On average, the defocus term (Z_2^0), astigmatism, or higher-order aberrations did not change systematically with accommodative demand in Crystalens eyes. As found for paraxial defocus, the effective defocus in Crystalens eyes did not show significant differences between conditions: 0.34 ± 0.48 D (far), 0.32 ± 0.50 D (intermediate), and 0.34 ± 0.44 D (near). Depth of focus was statistically significantly higher in the Crystalens eyes than in the control groups.**

• CONCLUSIONS: **The accommodative response of eyes implanted with the Crystalens accommodative IOLs, measured objectively using laser ray tracing aberrometry, was lower than 0.4 D in all eyes. Several subjects showed changes in astigmatism, spherical aberration, trefoil, and coma with accommodation, which must arise from geometrical and alignment changes in the lens with accommodative demand. Pseudoaccommodation from increased depth of focus may contribute to near vision functionality in Crystalens-implanted patients.** **(Am J Ophthalmol 2014;157:1077–1089. © 2014 by Elsevier Inc. All rights reserved.)**

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WITH AGING, THE CRYSTALLINE LENS FIRST LOSES its capability to accommodate to near and far objects (presbyopia), and later it loses transparency (cataract). An emerging solution for presbyopia and cataract correction are accommodating intraocular lenses (A-IOLs), artificial lenses that replace the aged crystalline lens of the eye, ideally mimicking the dynamic focusing capability of the young human crystalline lens in response to the ciliary muscle contraction,[1–4] and that restore both lens transparency and accommodation. Multiple A-IOL designs have been proposed, ranging from Food and Drug Administration-approved A-IOLs to conceptual proposals, and relying on various principles of operation (axial shifts, lateral shifts, or curvature-changing surfaces).[1] To date, the most generalized A-IOL designs rely on an axial shift of the intraocular lens (IOL). The lenses consist of either a single optical element expected to move forward (eg, the Crystalens A-IOL by Bausch & Lomb, Rochester, New York, USA)[3] or 2 optical elements expected to increase their separation axially (e.g., Synchrony by, Abbot Medical Optics (AMO) Inc., Santa Ana, California, USA),[4] in response to an accommodative stimulus.

Most clinical evaluations of performance of A-IOLs primarily are based on the patient's visual function, that is, testing of near visual acuity, reading tests, through-focus curves, or subjective measurements of accommodation.[3,5–8] Although these measurements assess visual performance at different distances, the results provided by these tests generally cannot conclude whether the lenses are actually working according to their functional mechanism. In fact, although several subjective studies report functional near vision with the Crystalens, studies using ultrasound biomicroscopy,[9,10] partial coherence interferometry,[11] and

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more recently, comprehensive quantitative 3-dimensional (3-D) optical coherence tomography (OCT) imaging[12] show irrelevant forward shifts of the A-IOL with accommodation. Different studies have shown than the subjective accommodative response after Crystalens A-IOL implantation ranged from 0.44 to 2.36 diopters (D), which was close to the magnitude of standard monofocal IOLs (range, ± 0.85 to ± 1.82 D).[6,10,13,14] Subjective accommodation measurements therefore have proved not very accurate for assessing the accommodative response, because these methods do not differentiate the functional range of near vision attributable to the depth of focus of the eye. Alternatively, dynamic photoretinoscopy, and particularly dynamic autorefraction, have proved to be rapid and repeatable techniques to assess the accommodation response.[15–18] Langenbucher and associates showed a mean accommodative response of 1.00 ± 0.44 D using photorefraction in patients implanted with the 1CU A-IOL (HumanOptics AG, Erlangen, Germany).[17] Recently, Zamora-Alejo and associates showed no change with accommodative effort in the spherical equivalent in patients implanted with the Crystalens HD.[19]

Besides potential axial displacements of the A-IOL, different factors (pupil size, residual defocus, astigmatism, and higher-order aberrations [HOAs]) may contribute to an expansion of the ocular depth of focus,[13,14,20] allowing some near vision functionality. Aberrometry therefore seems to be a highly suitable objective technique to evaluate optical performance of A-IOLs, including potential accommodative responses and the factors that may result in a potential pseudoaccommodation.[21–25] Static and dynamic aberrometry have been used in the past to assess the change of aberrations with aging[21,22] or accommodation,[23,24] as well as the impact of aberrations on the accommodative lag in young subjects.[25] In addition, aberrometry has been used extensively to evaluate optical performance in patients implanted with monofocal IOLs[26,27] and to estimate the impact of the IOL design on depth of focus.[28–30] However, whereas optical bench studies and ray-tracing simulations analyzed optical quality in A-IOLs,[28,31] there are few reports in the literature on the optical aberrations in eyes implanted with A-IOLs. Using dynamic Hartmann-Shack aberrometry, Dick and Kaiser found small changes in defocus in patients implanted with the Crystalens AT-45 (Bausch & Lomb) and 1CU (HumanOptics AG) A-IOLs.[32] Wolffsohn and associates reported some changes in ocular aberrations (defocus, astigmatism, coma, and trefoil) with increased accommodative demand in eyes implanted with the Tetraflex A-IOL (model KH-3500; Lenstec, St. Petersburg, Florida, USA).[33]

Although quantification of the 3-D position of the A-IOL with accommodation has proved to be an ideal tool to assess whether the mechanism of operation of the A-IOL complies with the expected design,[12] aberrometry will be essential to understand the causes of eyes seeming to gain near vision functionality with these A-IOLs. In fact, a future link between geometrical factors and optical outcomes may be established by means of customized eye models.[34,35] In this study, we measured ocular aberrations for different accommodative demands in 22 eyes implanted with Crystalens AO A-IOL. The absolute amounts of aberrations and their change with accommodation were compared with those of a young control group and those of pseudophakic control group of patients implanted with monofocal IOLs. These measurements allowed evaluation of the objective accommodative response, change of aberrations, and depth of focus in Crystalens A-IOL eyes at different accommodative demands and comparison of the outcomes with the young lens (accommodative response, aberrations, and depth of focus) and nonaccommodating IOLs (aberrations and depth of focus).

METHODS

ALL ENROLLED PATIENTS PROVIDED INFORMED CONSENT after they have been informed on the nature and consequences of the study. The protocols were approved by the institutional review boards of the Fundación Jiménez-Díaz, Madrid, Spain, and complied with the tenets of the Declaration of Helsinki.

• **PATIENTS, SURGERY, AND ACCOMMODATIVE INTRAOCULAR LENSES:** Twenty-two eyes from 11 patients were measured (mean age, 75 ± 4 years; range, 67 to 81 years; mean spherical equivalent, −0.5 ± 0.4 D; range, −1.25 to 0.75 D) in this prospective, observational study. Consecutive patients scheduled for cataract surgery with good general health and meeting the inclusion criteria (age older than 50 years, manifest astigmatism less than 1.5 D, and bilateral cataract considered as the sole cause of visual acuity decrease) were invited to participate. The same cohort also followed quantitative 3-D OCT patients for another study.[12]

Patients were implanted with the Crystalens AO A-IOL. This lens has a biconvex single-optic design, with aspheric anterior and posterior surfaces (nominally aiming at 0 IOL aberration, according to the manufacturer). The IOL power (selected using the SRK/T or the Holladay II formula, or both) of the implanted IOLs ranged from 19.50 to 24.50 D.

All procedures were performed by the same surgeon (S.D.) using standard phacoemulsification under local anesthesia The IOLs were implanted using a purpose-designed injector through a clear sutureless corneal incision created in superior–temporal and superior–nasal locations in the right and left eyes, respectively, and enlarged to approximately 2.8 mm. Anterior curvilinear capsulorrhexis (6.5-mm intended diameter) was created manually. All surgeries were uneventful, and all IOLs were implanted successfully in an intracapsular manner. More information on the lens and surgical procedures in this group of patients can be found in an earlier publication.[12]

• **CONTROL GROUPS: YOUNG CONTROL GROUP AND MONOFOCAL INTRAOCULAR LENS GROUP:** In addition to the patients implanted with A-IOLs, we also measured wave aberrations in young eyes (n = 17; mean age, 28 ± 4 years; range, 21 to 34 years; mean spherical equivalent, −0.2 ± 0.6 D; range, −1.0 to +1.25 D) under natural conditions and similar accommodative demands as those for Crystalens patients. Subjects were recruited specifically for this study among normal volunteers, following a standard ophthalmologic examination, and signed institutional review board-approved informed consent forms before participating in the study.

An additional control group included an aged-matched group of pseudophakic patients implanted with monofocal IOLs (n = 17; mean age, 74 ± 9 years; patients implanted with Tecnis (Abbot Medical Optics (AMO) Inc., Santa Ana, California, USA) and AcrySof (Alcon Research Labs, Fort Worth, Texas, USA) aspheric IOLs). Patients had participated in a previous study,[27] in which ocular aberrations had been measured at 2 different wavelengths to investigate chromatic aberrations using the same aberrometry system. Patients in the monofocal IOL group underwent surgery performed by the same surgeon (S.D.) as the Crystalens patients. The IOLs were implanted using a purpose-designed injector through a clear sutureless corneal incision (2.2 mm) created in superior–temporal and superior–nasal locations in the right and left eyes, respectively. A 6.0-mm continuous curvilinear capsulorrhexis was made under viscoelastic material. A detailed description of the sample and procedures was provided in a prior publication.[27]

• **LASER RAY TRACING MEASUREMENTS:** In this study, total wave aberrations were measured in Crystalens A-IOL implanted patients 3 months after surgery using a custom-developed laser ray tracing (LRT) optical system for 3 different accommodation stimuli. Measurements were conducted in 2 sessions. In a first session, measurements were performed under natural conditions. In a second session, measurements were obtained under instillation of phenylephrine, which allowed larger pupils without paralyzing the ciliary muscle. The same instrument was used to measure aberrations under natural conditions and 3 different accommodation stimuli in the young eyes and under dilated pupils (tropicamide 1%) and relaxed accommodation in monofocal IOL eyes. Figure 1 summarizes the conditions of the different measurements obtained in each group of patients.

The LRT technique measures the ray aberrations at the retinal plane (incoming aberrometry), and it was first described in detail in previous publications.[36,37] Illumination was provided by an infrared laser diode at

	Test Group	Control Groups	
	Crystalens	*Monofocal IOL*	*Young*
Relaxed accommodation	√	√	√
Stimulated accommodation (1.25/2.5 D)	√	--	√
Natural viewing	√	--	√
Dilated pupil (phenylephrine)	√	--	--
Dilated pupil (tropicamide)	--	√	--

FIGURE 1. Chart showing the conditions of the different measurements obtained in each group of patients (Crystalens, monofocal intraocular lenses [IOLs], and young). D = diopters.

785 nm (Schäfter + Kirchhoff, Hamburg, Germany). Maximum energy exposure was 6.8 μW. The beam samples the pupil sequentially, and the sampling pattern can be configured by software.[37] A sampling pattern consisting of 37 entry positions arranged in a hexagonal configuration within the pupil was used for this study. The sampling pattern was adjusted by software to fit the pupil of the patient's eye. In Crystalens eyes, the pupil ranged from 4 to 6 mm after inducing mydriasis (phenylephrine) and from 2 to 4 mm in natural conditions. In young control eyes, the natural pupil ranged from 4 to 6.5 mm (natural conditions), and in the monofocal IOL eyes, the pupil ranged from 4 to 6 mm (tropicamide 1%). The eye's pupil was monitored during measurements with a charge-coupled device (CCD) camera conjugate to the pupil to ensure correct alignment between the pupil center and the optical axis of the setup, and therefore a line-of-sight measurement reference. A high-sensitivity CCD camera (Retiga 2000-R; QImaging, Surray, British Columbia, Canada) captured the retinal aerial images corresponding to each entry pupil beam. In addition to recording the retinal aerial images, the CCD camera displays the retinal image in real time, allowing users to find objectively the best focus position while assessing the aerial image for a centered ray. During the measurement, the retinal camera is synchronized with the scanner and pupil camera. The acquisition time is approximately 1.5 seconds for an entire typical run. For the purposes of this study (static measurements of aberrations under steady accommodation), an open-field external fixation channel was incorporated in the LRT setup to stimulate accommodation. Figure 2 shows a schematic view of the system, including the accommodation stimulus. The subjects viewed the stimulus monocularly (the contralateral eye was covered with a patch during the measurement). The desired accommodative demand was produced by changing the fixation distance. The far fixation target (4 m) was the middle letter in the last line seen by each patient in an Early Treatment Diabetic Retinopathy chart (typically corresponding to 20/25 visual acuity). The intermediate and near fixation targets were the middle word of the last

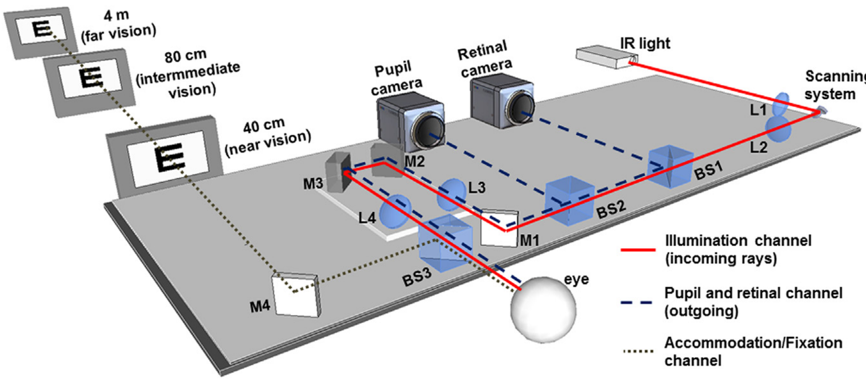

FIGURE 2. Schematic diagram of the laser ray tracing aberrometer. BS = beam splitter; L = lens; M = mirror.

line read by each patient in Early Treatment Diabetic Retinopathy test intermediate vision (80 cm; equivalent to 1.25 D) and near vision (40 cm; equivalent to 2.5 D) charts, respectively. The size of the stimulus therefore was adjusted to the visual acuity of each patient and condition. Each set of measurements consisted of 5 runs under the same conditions for every fixation target (far, intermediate, and near), and the results presented are the average of 5 repeated measurements.

• **DATA ANALYSIS:** Wave aberrations were fitted by Zernike polynomials expansions up to the sixth order. The change of defocus (Z_2^0), astigmatism (Z_2^2 and Z_2^{-2}), coma (Z_3^1 and Z_3^{-1}), trefoil (Z_3^3 and Z_3^{-3}), and spherical aberration (Z_4^0) with accommodative demand were analyzed specifically. Root mean square (RMS) also was used to report the magnitude of HOAs (excluding tilt, defocus, and astigmatism) and of certain characteristic aberrations (astigmatism, coma, and trefoil). When averaging individual Zernike coefficients across eyes, the mirror symmetry terms were flipped in right eyes to account for the enantiomorphism of the right and left eyes.

The accommodative response was obtained as the difference between the accommodative demand and the measured effective defocus. The effective defocus takes into account potential interactions between the second-order Zernike defocus term and the fourth-order Zernike spherical aberration, as well as potential changes in pupil diameter with accommodation, and was defined as:

$$M = \frac{-4\sqrt{3}C_2^0 + 12\sqrt{5}C_4^0 - 24\sqrt{7}C_6^0}{R^2} \quad (1)$$

Previous studies have shown that the spherical error computed using Equation 1 agrees well with that computed from the best focus using retinal plane image quality metrics.[25]

Unless otherwise noted, the analysis was carried out for a 4-mm pupil diameter for all eyes (under dilated pupils) and for the natural pupil diameter in each eye and condition (under natural viewing conditions).

Additionally, the astigmatism (C) and its angle (α) were analyzed from Zernike polynomials expansion by using Equation 2:

$$J_0 = \frac{-2\sqrt{6}C_2^2}{R^2}; \qquad J_{45} = \frac{-2\sqrt{6}C_2^{-2}}{R^2}; \qquad C = -2\sqrt{J_0^2 + J_{45}^2}; \quad \alpha = \arctan\frac{\frac{J_{45}}{J_0}}{2} \quad (2)$$

The point spread function, the modulation transfer function, and the optical transfer function were computed using Fourier optics from Zernike coefficients using routines written in Matlab (MathWorks, Natick, Massachusetts, USA).

Depth of focus (DoF) was estimated from through-focus objective optical quality. The optical quality metric used in the computations was visual Strehl.[38–40] Visual Strehl was computed as the volume under the visual modulation transfer function (modulation transfer function weighted by a general neural transfer function) normalized to diffraction limit. Visual Strehl was evaluated through-focus in 0.125-D defocus steps. All computations considered HOAs up to the sixth order and cancelled the astigmatism terms. Computations were carried out for the natural pupil size, as well as for a fixed 3-mm pupil diameter for comparison across subjects. Two standard definitions of DoF were used, one based on a relative metric[40] and the other on an absolute metric.[41] DoF was defined as the dioptric range for which visual Strehl was at least 50%,[40] the maximum visual Strehl value in the through-focus Strehl curve (relative definition), and as the dioptric range for which visual Strehl was more than 0.12 (absolute definition).[41]

Univariate analysis (independent-samples Student *t* test) was used to evaluate the differences in the evaluated parameters across different accommodative demands. Differences between aberrations and DoF in eyes implanted with A-IOLs, young subjects, and eyes implanted with monofocal IOLs were analyzed with a 1-way analysis of variance.

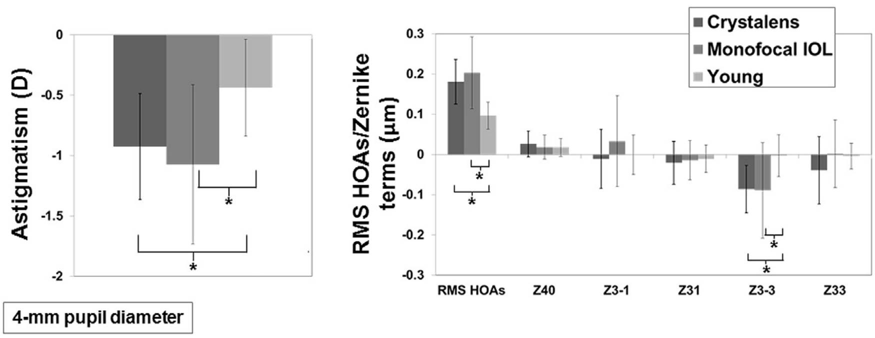

FIGURE 3. Graphs showing (Left) astigmatism and (Right) higher-order Zernike terms and orders in the accommodative intraocular lens group (IOLs; Crystalens) and control group (monofocal IOLs and young) for the unaccommodated state, averaged across eyes. Data are for 4-mm pupils. D = diopters; HOA = higher-order aberration; RMS = root mean square. *Statistical significance at $P < .005$.

TABLE. Percentage of Some Relevant Higher-Order Aberration Terms (Z_4^0, Z_3^{-1}, Z_3^1, Z_3^{-3}, and Z_3^3) to Total Higher-Order Aberration Root Mean Square in the Unaccommodated State for the Crystalens (Accommodative Intraocular Lens), Monofocal Intraocular Lens, and Young Groups

	Crystalens (%)	Monofocal IOL (%)	Young (%)
Z_4^0	10.13	7.35	21.20
Z_3^{-1}	4.17	13.15	0.78
Z_3^1	7.87	0.74	12.75
Z_3^{-3}	33.15	35.72	3.39
Z_3^3	14.98	20.21	5.08

IOL = intraocular lens.

RESULTS

• **INDIVIDUAL ABERRATIONS: UNACCOMMODATED STATE:** Figure 3 shows astigmatism and relevant higher-order Zernike terms and orders in Crystalens and control groups (monofocal IOL and young) for the unaccommodated state, averaged across eyes in each group (for 4-mm pupils). We found significant differences ($P < .005$) in astigmatism, HOA RMS, and vertical trefoil (Z_3^{-3}) between IOL groups (Crystalens A-IOL and monofocal IOL) and the young control group. The average HOA RMS wavefront error was 0.18 ± 0.05 μm (range, 0.06 to 0.28 μm) in Crystalens eyes, 0.20 ± 0.08 μm (range, 0.11 to 0.47 μm) in monofocal IOL eyes, and 0.09 ± 0.04 μm (range, 0.03 to 0.17 μm) in young eyes, for 4-mm pupil diameters. Repeated wave aberration measurements were highly reproducible within each subject: average HOA RMS standard deviations for repeated measurements were 0.05 μm, 0.04 μm, and 0.03 μm for Crystalens, monofocal IOL, and young control eyes, respectively.

The Table shows the contribution of selected HOAs (Z_4^0, coma [Z_3^{-1}, Z_3^1], and trefoil [Z_3^{-3}, Z_3^3]) to total RMS. Vertical trefoil (Z_3^{-3}) was the predominant HOA in the Crystalens group (−0.08 μm; 33.15% of the total RMS) and in the monofocal IOL control group (−0.09 μm; 35.73% of the total RMS) and was significantly higher ($P < .0001$) than in the young control group (−0.003 μm; 3.39% of the total RMS). Individual coma Zernike coefficients were not statistically significantly different between the Crystalens and control groups (monofocal IOL and young). The coma RMS was significantly higher ($P < .005$) in the Crystalens group (0.08 ± 0.04 μm) and in the monofocal IOL group (0.10 ± 0.07 μm) than in the young control group (0.05 ± 0.02 μm). Spherical aberration was not statistically significantly different across the 3 groups (0.02 ± 0.03 μm in the Crystalens group, 0.02 ± 0.03 μm in the monofocal IOL group, and 0.02 ± 0.02 μm in the young group), indicating that, on average, aspheric designs correct for corneal spherical aberration in a similar proportion than the crystalline lens in young subjects. Nevertheless, because of the lower amount of other aberrations, the contribution of spherical aberration to HOA was much higher in the young control group (21.20% of the total RMS).

• **INDIVIDUAL ABERRATIONS: CHANGES WITH ACCOMMODATIVE STIMULUS:** Figure 4 shows average ocular second- and higher-order Zernike coefficients and the corresponding wave aberration maps (excluding tilt, but including defocus, astigmatism, and HOAs; and excluding tilt, defocus, and astigmatism, but including HOAs) for Crystalens eyes (Top: A, B, C) and for young eyes (Bottom: D, E, F) for far, intermediate (1.25 D), and near (2.5 D) vision, respectively, for 4-mm pupil diameters, under phenylephrine (Crystalens) presence and natural conditions (young control). In the Crystalens group, wave aberrations maps were similar across accommodative demands, whereas in the young control group, the wave aberration maps show drastic changes (in defocus, but also, to a lesser extent, in HOA). On average, the defocus term (Z_2^0), astigmatism, or HOAs did not change systematically with accommodative demand in Crystalens eyes. However, as expected, young eyes showed highly statistically significant

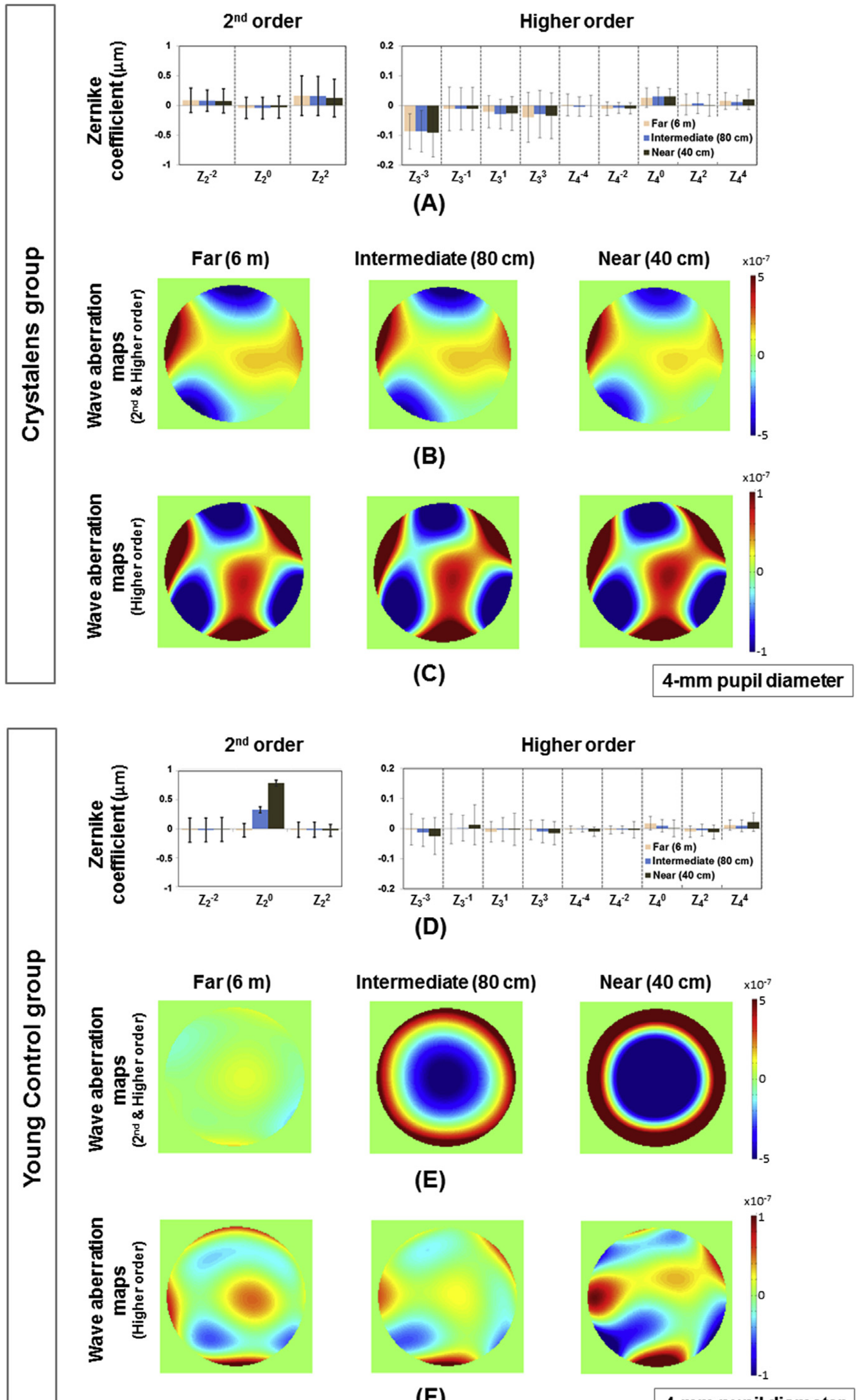

FIGURE 4. Average Zernike coefficients and wave aberration maps for different accommodative demands in Accommodative Intraocular Lenses (Crystalens) and young control groups. (Top) Crystalens group (A, B, and C). (Bottom) Young control group (D, E, and F). Data are for phenylephrine (Crystalens) and natural (young) conditions, and for 4-mm pupils. Zernike coefficients are shown up to the fourth order. Wave aberration maps are calculated from average Zernike coefficients up to the fifth order, excluding piston and tilt (B, E), and excluding piston, tilt, defocus, and astigmatism (C, F).

changes in the defocus term ($P < .001$) and in the spherical aberration (Z_4^0), which shifted toward less positive values with accommodation ($P < .005$). Additionally, vertical trefoil (Z_3^{-3}; $P = .09$), vertical coma (Z_3^{-1}; $P = .02$), and secondary vertical astigmatism (Z_4^{-4}; $P = .05$) showed changes with accommodation in the young control group.

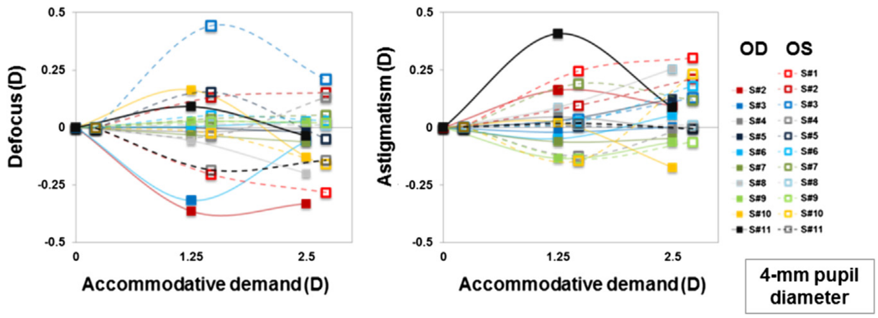

FIGURE 5. Graphs showing relative change in (Left) defocus and (Right) astigmatism, in diopters (D), in all Crystalens (accommodative intraocular lenses) eyes as a function of accommodative demand. Data are for measurements under phenylephrine and 4-mm pupil diameters. OD = right eye, solid symbols; OS = left eye, open symbols.

Figure 5 shows the accommodative change of (Left) defocus and (Right) astigmatism, expressed in diopters, in all Crystalens eyes under phenylephrine. Some Crystalens eyes (24%) showed significant changes in defocus with accommodative demand (S#1 (OS), S#2 (OD), S#2 (OS), S#3 (OD), and S#3 (OS)), although the direction for the change differed across subjects. Although an accommodative response consistent with effective near accommodation should show a negative shift in the Zernike defocus term (as seen in the control group), 7 Crystalens eyes (S#2 (OS), S#3 (OS), S#4 (OS), S#5 (OS), S#7 (OS), S#10 (OD), and S#11 (OD)) actually changed defocus in the opposite direction. The largest change in defocus with accommodative demand (approximately 0.4 D) occurred for S#2 (OD). Additionally, some subjects (14%) showed significant changes in astigmatism with different accommodative demands (S#1 (OS), S#10 (OS), and S#11 (OD) for intermediate). A larger change in defocus and astigmatism generally was observed for a 1.25-D accommodative demand than for a 2.5-D accommodative demand. The absolute average defocus shift across accommodative demands was 0.11 D between intermediate and far and 0.10 D between near and far. The absolute average difference in astigmatism was 0.09 D between intermediate and far and 0.10 D between near and far.

Figure 6 shows the change of the HOA RMS, spherical aberration (Z_4^0), coma-like terms (Z_3^1 and Z_3^{-1}), and trefoil-like terms (Z_3^3 and Z_3^{-3}) with accommodative demand in all Crystalens subjects for 4-mm pupil diameters and under phenylephrine. Most eyes showed slight changes in aberrations with accommodative demand. In many cases, the largest change occurred for 1.25 D of accommodative demand and decreased for 2.5 D of accommodative demand. Eye S#11 (OD) showed the largest change in HOA RMS (approximately 0.05 μm) for 1.25 D of accommodative demand. This eye showed significant increase in coma, trefoil, and spherical aberration ($P < .05$). Conversely, other eyes (eg, S#1 OD) also showed significant changes ($P < .05$) in coma, trefoil, and spherical aberration, but toward more negative values.

• **WAVE ABERRATIONS WITH PHENYLEPHRINE AND NATURAL VIEWING CONDITIONS:** Measurements of defocus and astigmatism (and its angle) measured in different sessions and conditions (phenylephrine and natural viewing) in Crystalens eyes did not show significant differences between conditions (Figure 7). The average deviations were less than 0.01 D in defocus (mean defocus, 0.037 D and 0.047 D for phenylephrine and natural conditions, respectively), less than 0.037 D in astigmatism (mean astigmatism, −0.95 D and −0.91 D for phenylephrine and natural conditions, respectively), and less than 8.3 degrees in astigmatic angle (−4 and 4.3 degrees with phenylephrine and natural conditions, respectively).

• **CHANGE IN ACCOMMODATIVE RESPONSE WITH ACCOMMODATIVE DEMAND:** Figure 8 shows the accommodative response in (Left) Crystalens eyes and (Right) young control eyes estimated for natural viewing conditions using Equation 1. For Crystalens eyes, on average, the effective defocus (M) did not show significant differences between conditions: 0.03 ± 0.33 D (intermediate-far) and 0.03 ± 0.32 D (near-far). Mean pupil diameter (Crystalens group) was 3.90 ± 0.64 mm for far, 3.72 ± 0.47 mm for intermediate, and 3.59 ± 0.64 mm for near. As found for paraxial defocus, most Crystalens eyes did not show significant accommodative responses. In addition, although some Crystalens eyes (14%) showed significant accommodative responses in the expected direction (S#1 (OS), S#2 (OD), S#7 (OD)), other eyes (14%) responded in the opposite direction (S#3 (OS), S#7 (OS), and S#11 (OD)). Figure 7 (Right) shows for comparison the effective defocus changes in the young control group. The accommodative response in young eyes was on average −0.79 ± 0.25 D (intermediate-far) and −1.67 ± 0.30 D (near-far). The accommodative lag varied across subjects and was on average 0.46 ± 0.25 D (range, 0 to 0.7 D) and 0.82 ± 0.30 D (range, 0 to 1.03 D) for 1.25- and 2.5-D stimuli, respectively. Mean pupil diameter in the young control group was 5.62 ± 0.83 mm for far, 5.45 ± 0.76 mm for intermediate, and 5.17 ± 0.69 mm for near.

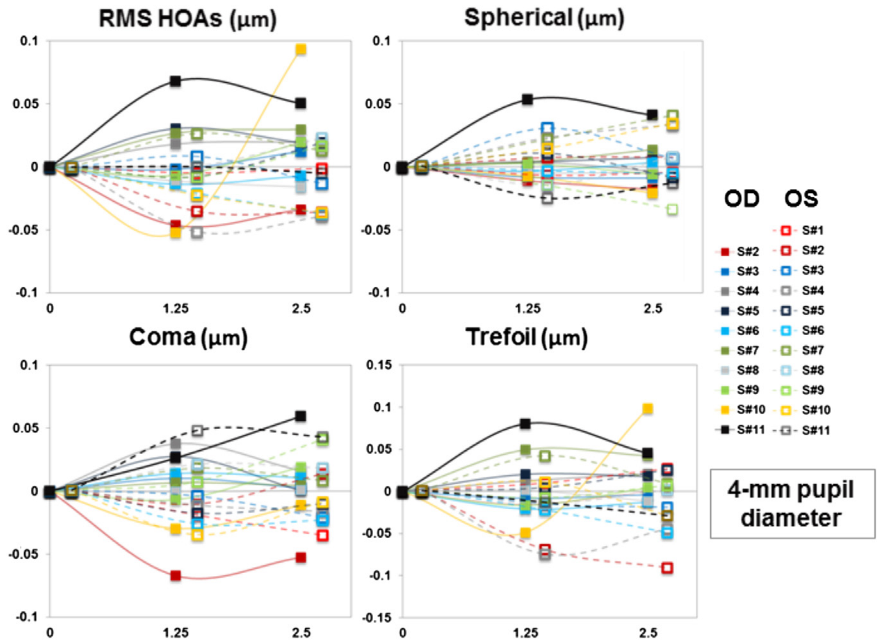

FIGURE 6. Relative change in (Top left) root mean square (RMS) higher-order aberrations (HOAs), (Top right) spherical, (Bottom left) coma, and (Bottom right) trefoil of all Crystalens (accommodative intraocular lenses) subjects as a function of accommodative demand. Data are for measurements under phenylephrine and 4-mm pupil diameters. OD = right eye, solid symbols; OS = left eye, open symbols.

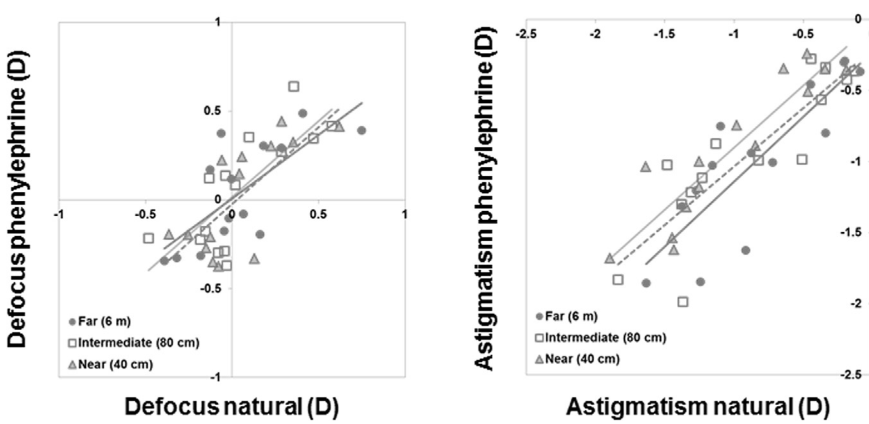

FIGURE 7. (Left) Scatterplot showing defocus for natural conditions versus defocus with phenylephrine in accommodative intraocular lenses (Crystalens group). (Right) Scatterplot showing astigmatism for natural conditions versus astigmatism with phenylephrine in accommodative intraocular lenses (Crystalens group). Lines are linear regressions of the data. D = diopters.

• DEPTH OF FOCUS: Figure 9 shows the through-focus visual Strehl in the Crystalens group (Top left, 3-mm pupil; Bottom left, natural pupil), the monofocal IOL control group (Top middle, 3-mm pupil), and the young control group (Top right, 3-mm pupil; Bottom middle, natural pupil), as well as the average through-focus Strehl ratio for all groups and conditions (Bottom right). Maximum visual Strehl in the Crystalens group (0.42 ± 0.15 for natural pupil diameter and 0.61 ± 0.11 for 3-mm pupils) was significantly lower ($P = .05$ and $P < .0005$, for natural pupil and 3-mm pupil diameters, respectively) than in the young control group (0.56 ± 0.21 for natural pupil diameter and 0.88 ± 0.08 for 3-mm pupils) and marginally lower ($P = .09$) than in the monofocal IOL group. Despite the large intersubject variability (arising from differences in the subjects' HOA and pupil dynamics), the differences in optical quality between the Crystalens and young control groups are attenuated with natural pupils, mostly as a result of the age-related smaller pupil size of Crystalens eyes (3.90 ± 0.64 mm, unaccommodated state) in

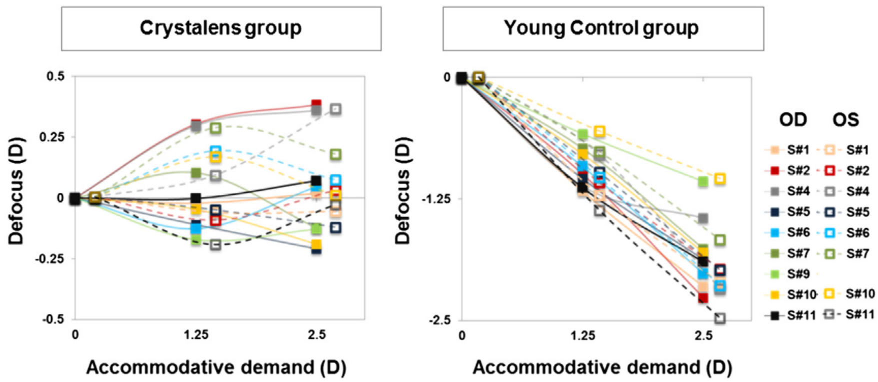

FIGURE 8. Graphs showing accommodative response as a function of accommodative demand, relative to 0, computed from the corresponding changes in defocus, spherical aberration, and pupil diameter, under natural conditions: (Left) Crystalens (accommodative intraocular lenses) group, (Right) young control group. D = diopters; OD = right eye, solid symbols; OS = left eye, open symbols.

comparison with the young eyes (5.62 ± 0.83 mm, unaccommodated state).

DoF was estimated from the visual Strehl through-focus curve for each eye. Figure 10 shows the DoF for relative and absolute definitions (Top, 3-mm pupil; Bottom, natural pupil). The Crystalens group shows the largest DoF in all conditions compared with the control groups. For a 3-mm pupil, the relative DoF definition yielded a value of 1.02 ± 0.15 D for the Crystalens group and 0.77 ± 0.12 D for the young control group. DoF of the Crystalens group was statistically significantly higher than the DoF of the monofocal IOL group ($P = .04$, relative definition, 3-mm pupil) and than the DoF of the young control group ($P < .0005$, relative definition, 3-mm pupil; $P < .005$; absolute definition, natural pupil; $P < .0005$).

DISCUSSION

USING LRT ABERROMETRY, WE MEASURED ACCOMMODAtive response, monochromatic aberrations, optical performance, and DoF in patients implanted with the Crystalens A-IOL for different accommodative demands. We found that the accommodative response was less than 0.4 D (0.03 D on average), and in fact was negative in 14% of the patients. In comparison, the accommodative response in young eyes, using the same system, reached the full accommodative demands (1.25 D and 2.5 D in some eyes), and was 0.8 D and 1.7 D on average, with average values and intersubject variability consistent with previous reports.[25,42–44] We also found that HOAs (particularly vertical trefoil) were larger (approximately 30%), and DoF (for 3-mm pupils) was wider (by approximately 0.2 D, on average) in eyes implanted with Crystalens A-IOLs, with respect to a young control group. Although the increase of vertical trefoil was similar in an aged-matched group of patients implanted with monofocal IOLs, horizontal coma and horizontal trefoil tended to be slightly higher in the Crystalens AO than the monofocal IOL group, resulting in a slight increase of DoF.

The optical findings in the eyes implanted with the Crystalens can be correlated with biometric findings obtained in a recent study using 3-D OCT-based biometry in the same group of eyes, both in terms of magnitude and direction of the A-IOL shifts.[12] In the previous study, we found that Crystalens axial shifts with accommodative demand ranged from 0.07 to −0.1 mm, consistent with the defocus shifts ranging from 0.43 to −0.36 D found in the current study. The positive shifts are opposite from the expected A-IOL shift and defocus changes, and the overall magnitudes are below clinical relevance. Our data therefore confirm that this A-IOL does not produce a relevant change in eye optical power by axial shifts of its position. Also, in keeping with the observation that the 1.25-D stimulus elicited relatively larger accommodative A-IOL shifts, we also found larger changes in defocus (and aberrations) for the 1.25-D intermediate accommodation demand in most subjects.

Some reports claim potential changes in the A-IOL surface curvature by flexure in the lens.[33] Although spherical aberration changed significantly in young accommodating eyes, we did not find, on average, significant changes in spherical aberration with accommodation in Crystalens eyes. Individually, most eyes did not show significant changes in spherical aberration with accommodative demand, although some showed significant shifts toward more positive values and others toward more negative values, indicating that, even if modifications in the A-IOL surface may occur leading to optical changes, these are not systematic, nor can they reliably produce the desired accommodative response. In fact, our estimates of accommodative response, integrating changes in defocus, spherical aberration, and pupil diameter, do not show functional accommodation in any of the eyes.

Crystalens and monofocal IOL eyes showed significantly higher amounts of astigmatism and HOAs than young eyes.

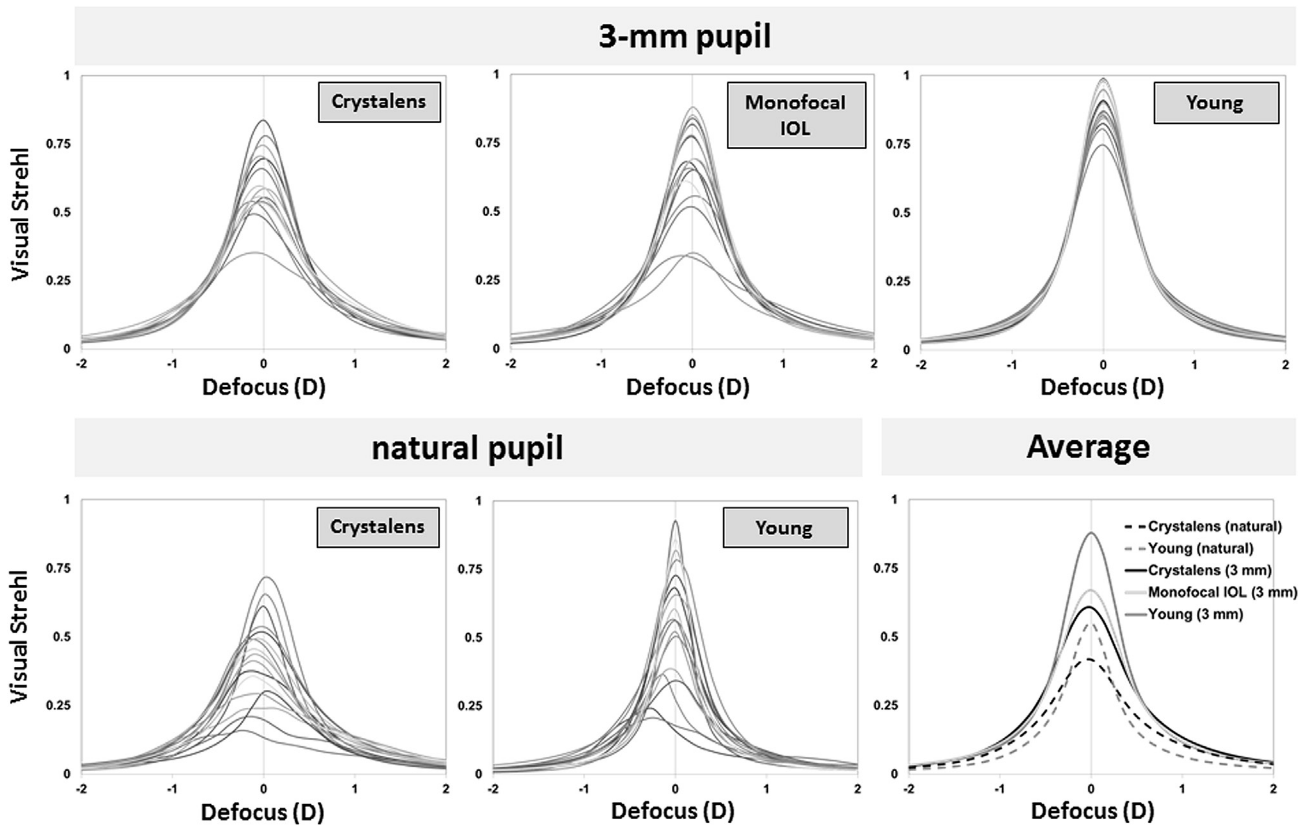

FIGURE 9. Graphs showing through-focus visual Strehl for (Left column) the Crystalens (accommodative intraocular lenses) group: (Top left) 3-mm pupil diameter, (Bottom left) natural pupil diameter), (Top middle) monofocal intraocular lens (IOL) group (3-mm pupil diameter), and (Top right and Bottom middle) young group ((Top right) 3-mm pupil diameter and (Bottom middle) natural pupil diameter). (Bottom right) Average through-focus groups for the Crystalens (accommodative IOL) group (black lines) and for the control groups (gray lines, monofocal IOL and young) for (solid) 3-mm and (dashed) natural pupil diameters. D = diopters.

The increased trefoil found both in Crystalens and monofocal IOL eyes may be associated with incision-induced corneal aberrations, as shown by prior studies.[45] However, the fact that trefoil increased with accommodative demand in some eyes suggests also some lenticular involvement. Increased astigmatism may be related to the incision, but also to tilt of the IOL. In a previous study, we characterized IOL tilt in eyes implanted with the Crystalens and its change with accommodative demand using quantitative 3-D OCT imaging in these eyes.[12] Very interestingly, in general, eyes with the higher amount of postoperative astigmatism, coma, and trefoil are those for which larger amounts of tilt were reported[12]: for example, S#10 (OS) showed the largest amount of astigmatism (0.75 ± 0.05 μm) and also large tilts around X and Y (tilt X = −4.86 ± 1.15 degrees; tilt Y = 9.10 ± 1.15 degrees). We found correlations between RMS HOAs ($r = -0.48$; $P = .038$), RMS astigmatism ($r = -0.47$; $P = .041$), and RMS trefoil ($r = -0.61$; $P = .005$) and the tilt around X for the unaccommodated state. Although not significant, we observed slight correlations between the RMS coma and the magnitude of tilt ($r = 0.37$; $P = .12$). In addition, we observed some trend between changes in aberrations and in tilt with accommodative demand: for example, astigmatism versus tilt around X for near vision ($r = 0.47$; $P = .04$) and coma versus tilt around X for near vision ($r = 0.38$; $P = .09$). Because 3-D biometry[12] and aberrometry were measured in different instruments (OCT and LRT, respectively), some differences in the accommodative response may occur, influenced by differences in the accommodation target (single letter vs word) and stimulus (Badal vs proximity), ambient illumination (0.2 vs 3.4 cd/m^2), and alignment of the subject. The high intersubject variability in the HOAs and their change with accommodation agrees with reports by Wolffsohn and associates in eyes implanted with another axial shift-based A-IOL (Tetraflex).[33]

The high amplitudes of accommodation measured by the push-up test, defocus curves, or reading performance in Crystalens eyes reported by some previous studies (ie, 2.42 D and 1.74 D, respectively)[5,46] may be confounded by multiple factors. It has been speculated that the functional visual performance in Crystalens eyes in fact may be achieved by pseudoaccommodation, rather than

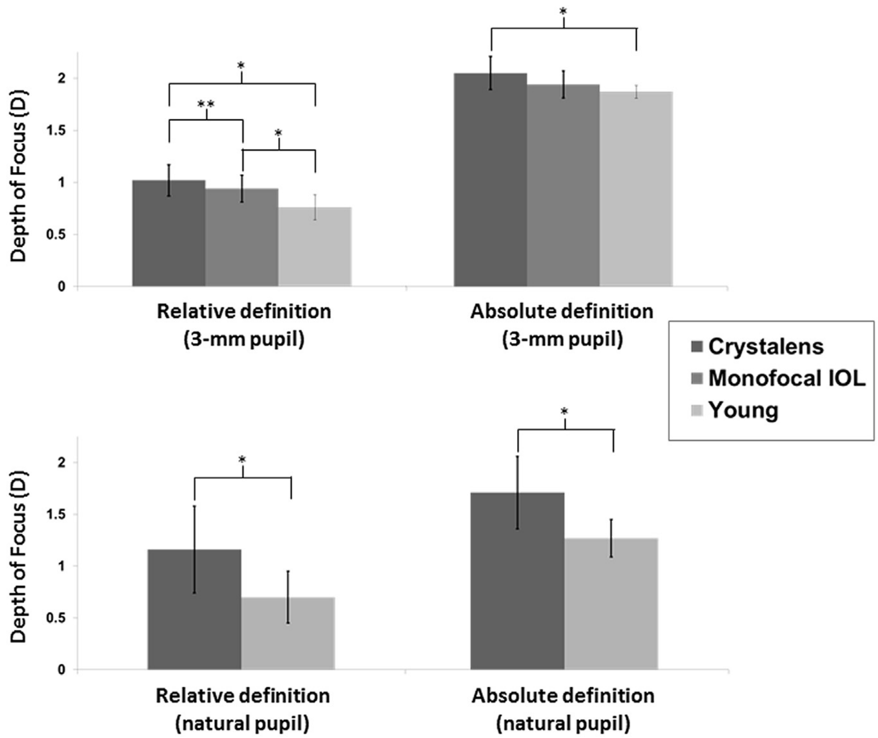

FIGURE 10. Bar graphs showing depth of focus for relative (50%) and absolute (visual Strehl threshold, 0.12) definitions for the Crystalens (accommodative intraocular lenses) group, monofocal intraocular lens group, and young group ((Top) 3-mm pupil, (Bottom) natural pupil). *Statistical significance at $P < .005$. **Statistical significance at $P < .05$. D = diopters; IOL = intraocular lens.

true optical power changes.[6] Increased aberrations (such as those produced by increased A-IOL tilt and corneal aberrations, as shown here) result in increased DoF. Using visual Strehl as an optical quality metric, we found that the DoF was expanded on average approximately 0.2 D over normal young eyes and 0.1 D over monofocal IOL eyes, with the differences being systematic and highly statistically significant. Although this amount may not represent a clinically relevant increase in DoF, the contrast achieved out of focus may produce additional functional near vision in these patients.

To sum up, LRT aberration measurements in eyes implanted with the Crystalens A-IOLs showed changes in objective accommodative response of less than 0.4 D and negative accommodative responses in 14% of the eyes, consistent with the reported small axial shifts (and backward shifts) of the A-IOL with accommodative demand. Several Crystalens eyes showed changes in astigmatism, spherical aberration, trefoil, and coma with accommodation, which must arise from geometrical and alignment changes in the lens with accommodative demand. These changes are highly variable across subjects in both magnitude and sign. However, the higher amount of aberrations in Crystalens eyes in comparison with young eyes, likely arising from A-IOL tilt and increased corneal aberrations, results in increased depth of focus, which may explain some functional near-vision performance in these eyes (by pseudoaccommodation, rather than by true accommodative changes in optical power). These measurements therefore shed light on the mechanisms of operation of the Crystalens A-IOL. The availability of full 3-D geometrical and biometrical characterization of these eyes will allow building of customized eye models, comparing predicted and measured optical aberrations, and specifically evaluating the contribution of the different factors to optical performance.

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Biosketch

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